

### **Remarks**

Claims 37, 42, 50 and 53 are hereby amended. No new matter is introduced by this amendment. Support for the amendments is provided by the claims as originally filed, and throughout the specification.

### **Rejections Under 35 USC §112, Second Paragraph**

Prior claims 9, 11-24, 27-31, 35 and 36 stood rejected under 35 USC §112, Second Paragraph as being indefinite.

Independent claims 37 and 52, and the claims dependant therefrom, address the issues of maintaining sterility in the system. In the Office Action of 12/22/2005, the Office asserts that the prior claims presented were indefinite under 35 USC 112, second paragraph, since it was not clear if the system was closed to input/output from the outside, or were closed into a chamber with specific conditions. This rejection is believed to be moot in view of the claims as amended.

Dependent claims 42 and 50 have been amended to remove the qualifier “in-line” from the filter element. Applicant believes these amendments render moot the rejection under 35 USC 112, second paragraph.

Applicant believes that these amendments address the prior rejection under 35 USC §112, Second Paragraph, and as such respectfully request these rejections be withdrawn.

### **Prior Art Rejections**

The previous claims stood rejected under a variety of prior art rejections, all based on 35 USC 103. Applicant believes the present amendment renders these rejections moot.

Hei (US patent 6,544,727) is cited by the Office as teaching a system for the decontamination of biological fluids, which is purported to render obvious the instant claims. Applicant respectfully disagrees with this conclusion. Hei describes methods and devices for the removal of psoralens from blood products, and that device is quite different from the one claimed by the Applicant. The Office interprets Hei as containing numerous mechanical elements, which are also found in Applicant’s invention, i.e., conduits, valves, temperature controls, etc. However, Hei does not teach all elements of the claimed device. The Office is reminded that “[t]he mere fact that each reference discloses some particular claimed elements is not sufficient

for obviousness without some direction from the prior art” *Ex parte Shepard and Gushue*, 118 U.S.P.Q. 536, 538 (PTO Bd. App. 1974). Applicant’s device includes *a plurality of sensors all adapted to the control module and individually adapted to either the supply module, the processing module or the cell module, the cell module sensor comprising a weight sensor*. The instant device is for enzymatic manipulation of blood cells, and the parameters of the reaction need to be controlled with precision. The weight sensor permits the device to accurately and precisely calculate and deliver the appropriate volumes of reagents. This feature is not taught by Hei, and the device of Hei can’t be adapted for the purposes described in the instant application. Of particular relevance is *Ex parte Clapp* (227 U.S.P.Q 972, B.P.A.I 1985) which states

“In the instant application, the Examiner has done little more than cite references to show that one or more elements or some combinations thereof, when each is viewed in a vacuum, are known. The claimed invention, however, is clearly directed to a combination of elements. That is to say, the appellant does not claim that he has invented one or more new elements but has presented claims to a new combination of elements. To support the conclusions that the claimed combination is directed to obvious subject matter either the references must expressly or impliedly suggest the claimed combination, or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.”

The Board concluded “Based upon the record, the artisan would not have found it obvious to selectively pick and choose elements or concepts from the various references so as to arrive at the claimed invention, without using the claims as a guide.” In the instant case, the simple fact that Hei teaches some common mechanical elements used in Applicants invention, does not rise to the level of rendering the instant claims obvious. Particularly so, where Hei is deficient in at least one of the claimed elements.

Inoue et al. discloses an apparatus for collecting blood cells. The apparatus oscillates to prevent clotting of the blood during collection. The weight of the collected blood is determined to assess the termination stage. Inoue et al. does not disclose processing of blood cells following

collection, and in no instance does Inoue et al. suggest that a weight sensor control the measured addition of reagents to react with blood cells. Accordingly, the combination of Hei and Inoue et al. does not disclose *a plurality of sensors all adapted to the control module and individually adapted to either the supply module, the processing module or the cell module, the cell module sensor comprising a weight sensor.*

The addition of Matkovich (United States Patent 5,126,054) still does not render obvious the instant claims. Matkovich does not add the element of *a plurality of sensors all adapted to the control module and individually adapted to either the supply module, the processing module or the cell module, the cell module sensor comprising a weight sensor.* Accordingly, Matkovich does not cure the deficiencies of Inoue et al and Hei, and in combination with these, still does not teach the invention claimed by Applicant.

The addition of Hudak (United States Patent 5,641,637) still does not render obvious the instant claims. Hudak does not add the element of *a plurality of sensors all adapted to the control module and individually adapted to either the supply module, the processing module or the cell module, the cell module sensor comprising a weight sensor.* Hudak is directed to an invention that accomplished the exact opposite of the instant invention. The Office asserts that Hudak would motivate a skilled artisan to provide rare cell genotype blood to hospitals. That may be true, but the instant specification clearly describes methods and apparatus for the removal of blood antigens, which is designed for the purpose of creating a universally histocompatible blood cell. Accordingly, Hudak does not cure the deficiencies of Inoue et al and Hei, and in combination with these, still does not teach the invention claimed by Applicant.

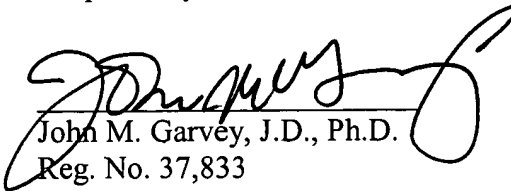
None of the above references, either alone or in combination, teach the invention claimed in the instant application. Accordingly, Applicant believes the claims as amended are free of the above cited art, and respectfully requests the various rejections under 35 USC 103 and 112 be withdrawn.

Application No.: 09/728,327  
Office Action Dated: June 21, 2006  
Applicant: Jorgenson, G.

Applicant submits that the present application is in condition for allowance and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number 617-342-4000. The Commissioner is hereby authorized to charge payment of any filing fees required in connection with the papers transmitted herewith, or credit any overpayment of same, to Deposit Account No. 50-3431 (Reference No. ZQI-102CON1).

Respectfully submitted,

Date: June 21, 2006

  
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